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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,429	04/02/1999	BRET A. SHIRLEY	5784-9	3707

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/285,429

Applicant(s)

SHIRLEY ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 21-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-34 is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 14 and 35-40 is/are rejected.
- 7) ☒ Claim(s) 11, 12 and 41-44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The finality of the previous Office Action is withdrawn due to a new ground rejection.

#### ***Status of the Claims***

2. Claims 1-14 and 21-44 are pending.

Applicants' amendment filed February 19, 2003 (Paper No. 25) is acknowledged, and applicant's response has been fully considered. Claims 1, 3-5 and 12 have been amended, and new claims 35-44 have been added. Therefore, claims 1-14 and 21-44 are examined.

#### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 102***

3. The previous rejection of claims 1-3, 6-10, 13 and 14 under 35 USC § 102(b), as being anticipated by Bontempo *et al.* (EP 0284249), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 4-5 in Paper No. 25.
4. The previous rejection of claims 1-8, 13 and 14 under 35 USC § 102(b), as being anticipated by Hwang-Felgner *et al.* (U. S. Patent 5,151,265), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 4-5 in Paper No. 25.
5. The previous rejection of claims 1-3 and 13 under 35 USC § 102(b), as being anticipated by Olefsky *et al.* (WO 96/40894), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 4-5 in Paper No. 25.

#### ***Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-8, 13, 14 and 35-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 9, 12, 13, 36-40, 45, 47, 48 of copending application US 2002/0172661 A1 (10/035,397). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-8, 13, 14 and 35-40 in the instant application disclose a pharmaceutical composition comprising a pharmaceutically active agent and a succinate buffer at a concentration of 7-45 mM. This is obvious in view of claims 1, 6, 9, 12, 13, 36-40, 45, 47, 48 of copending application which disclose a pharmaceutical composition comprising a monomeric interferon-beta solubilized in a low ionic strength formulation, wherein the formulation comprises a buffer (e.g., succinate at about 5 mM) to maintain a pH about 3.0 to about 5.0 and has an ionic strength not greater than about 60 mM. Since the claims of the instant application and those of the copending application are directed to a pharmaceutical composition comprising a pharmaceutically active agent and a succinate buffer, wherein the ionic strength of the composition is not greater than about 60 mM. Thus, claims 1-8, 13, 14 and 35-40 in present application and claims 1, 6, 9, 12, 13, 36-40, 45, 47, 48 of copending application are obvious variations of a pharmaceutical composition comprising a pharmaceutically active agent and a succinate buffer at a concentration of 7-45 mM.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-10, 13, 14 and 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Profitt *et al.* (EP 0317120, May 1989).

Profitt *et al.* teach the dry powder of a lipid solution containing Amphotericin B-DSPG (distearoylphosphatidylglycerol) complex was hydrated in aqueous buffer of 9% (w/v) lactose containing 10 mM sodium succinate at pH 5.5 to form liposomes for injection in the treatment of fungal infection, and the liposomes can be sterilized by filtration (page 4, lines 33-37; page 7, lines 25-46; claims 1-8, 13 and 35-40). During the preparation of Amphotericin B-DSPG complex, solutions of 2.5 M HCl and 2.5 M NaOH were added to the preparation to adjust pH (page 6, lines 54-page 7, line 10), thus the preparation contains sodium chloride (claims 9 and 10). The liposome Amphotericin B formulation can be lyophilized since the presence of lactose in the formulation serves to stabilize the structure of the liposome during lyophilization (page 9, lines 1-18; claim 14).

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8. Claims 1-5, 9, 10, 13 and 35-40 are rejected under 35 U.S.C. 102(e) as anticipated by Cleland *et al.* (US 2002/0004481 A1, filed June 11, 1998).

Cleland *et al.* teach an injectable nerve growth factor (NGF) microencapsulate composition, where the suspension of microspheres is prepared with a sterile solution, and the formulation may contain buffer such as succinate in the range of about 2 mM to about 100 mM (claims 1-5, 13 and 35-40) and pharmaceutically acceptable salt such as sodium chloride (paragraphs 0136 and 0137; claims 9 and 10).

9. Claims 11, 12 and 41-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

10. Claims 1-10, 13, 14 and 35-40 are rejected, and claims 11, 12 and 41-44 are objected. It appears claims 21-34 are free of prior art, thus are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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March 16, 2003

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